

### REMARKS

#### Status of the claims

Claims 1-8 and 11-20 are pending and under consideration in this application.

Claims 1, 11, and 17-20 have been amended by deletion of the redundant term "as depicted in Fig. 1".

No claims have been added or cancelled herein. Therefore, after entry of the present Amendment and Response, claims 1-8 and 11-20 will be pending and under consideration in this application.

None of the amendments made herein add new matter.

#### 35 U.S.C. § 112, first paragraph, rejection

Claims 17-20 stand rejected on the grounds of lack of enablement.

From the comments on page 2, line 13, to page 3, line 4, of the Office Action, Applicants understand the Examiner's position to be that the methods of the instant claims are not enabled because, in contrast to the method described in Amor et al., in the methods of the instant claims "any detectable immune response is determined to label a subject as "TB-positive". Applicants respectfully disagree with this position.

In the present claims it is stated that the presence of an immune response is an indication that the subject has a *Mycobacterium tuberculosis* infection. In other words, the presence of an immune response is not necessarily unequivocal proof of *Mycobacterium tuberculosis* infection. While not impossible, *in vivo* tests such as those specified by claims 17-20 (e.g., skin tests) are not simple to quantify and hence to establish appropriate "cut-off" values as in the *in vitro* antibody-detecting tests described in Amor et al. Frequently, after obtaining an indication of *Mycobacterium tuberculosis* infection using a test such as one of the present claims, one or more confirmatory tests are carried out. A conclusive diagnosis of *Mycobacterium tuberculosis* infection would in most cases only be made following the performance of more than one type of test.

From the comments on page 3, lines 5-15, of the Office Action, Applicants understand the Examiner's position to be that the specification is not enabling for "functional segments" of the polypeptides, i.e., polypeptide segments that have "*Mycobacterium tuberculosis* specific antigenic and immunogenic properties". While not agreeing with this position, in order to expedite prosecution of the instant application, Applicants have deleted the "functional" from claims 18-20 and have added a requirement that the relevant segments retain specific antigenic properties. Applicants submit that it would be an entirely routine endeavor for one skilled in the art to test whether any particular polypeptide segment of interest retained specific antigenic properties in view of the definition of the term "antigenic" in the specification, i.e., "capable of being recognized by either antibody molecules or antigen-specific T cell receptors (TCR) on activated effector T cells (e.g., cytokine-producing T cells or CTL) (page 7, lines 14-17)."

In light of these considerations, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

35 U.S.C § 112, second paragraph, rejection

Claims 1-8 and 11-20 stand rejected on the grounds of indefiniteness.

With respect to the statement on page 3, line 17, of the Office Action, Applicants point out that the presently pending claims do not specify polypeptides with conservative substitutions.

From the comments on page 3, line 19, to page 4, line 2, of the Office Action, Applicants understand the Examiner's position to be that the above-recited claims are indefinite because the "instant specification contains no working examples of the claimed invention showing that the claimed polypeptides of *M. tuberculosis* comprise the claimed antigenic and immunogenic properties."

Applicants respectfully disagree with this position. First, there is no absolute requirement for working examples in order to establish definiteness or any other patentability criterion. Moreover, it is not clear to Applicants how a working example could necessarily establish "definiteness" of some claim term. Notwithstanding these considerations, Applicants respectfully submit that the rejection is rendered moot by the above-mentioned cancellation of

the term "functional" from claims 17-20, its cancellation from claims 15 and 16, the cancellation of the requirement that a polypeptide or segment have "*Mycobacteria tuberculosis* specific antigenic and immunogenic properties" from claims 1, 2, and 11, and , where appropriate, the addition of a requirement that polypeptide segments retain antigenic properties. Applicants respectfully submit that the term "antigenic properties," in view of the above-quoted definition of "antigenic" in the specification, is perfectly clear.

In light of the above considerations, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

CONCLUSION

In summary, for the reasons set forth above, Applicants maintain that the pending claims patentably define the invention. Applicants request that the Examiner reconsider the rejections as set forth in the Office Action and permit the claims to pass to allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, applicants' undersigned representative can be reached at the telephone number listed below.

Please apply any charges or credits to deposit account 06-1050, referencing Attorney Docket No. 07763-042001.

Respectfully submitted,

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